

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS AG,
NOVARTIS PHARMA AG, and LTS
LOHMANN THERAPIE-SYSTEME AG,

Plaintiffs.

C.A. No. 14-cv-1104-RGA

v.

ZYDUS NOVELTECH INC.,

Defendant.

Memorandum Opinion

Daniel Silver, Esq., McCarter & English LLP, Wilmington, DE; Nicholas Kallas, Esq., Fitzpatrick, Cella, Harper & Scinto, New York, NY; Christopher Loh, Esq. (argued), Fitzpatrick, Cella, Harper & Scinto, New York, NY; attorneys for the Plaintiffs.

Ryan Newell, Esq., Connolly Gallagher LLP, Wilmington, DE; Charles Weiss, Esq. (argued), Holland & Knight; New York, NY; Judith Nemsick, Esq., Holland & Knight, New York, NY; attorneys for the Defendants.

August 7, 2015


ANDREWS, UNITED STATES DISTRICT JUDGE:

Plaintiffs filed a Hatch-Waxman patent infringement action against defendants Zydus Noveltch, Inc., Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. for infringing two patents for the "Exelon" transdermal system, which is used to treat dementia. (D.I. 15 at 6; D.I. 28 at p. 1; D.I. 1 at 4-6). Immediately after filing this case, Plaintiffs filed a parallel action in the District of New Jersey. (D.I. 15 at 6).

From 2011 to the present, this Court has resolved, or will resolve, a number of Exelon-related ANDA suits filed by Plaintiffs against other defendants. (No. 11-1077-RGA, D.I. 426; No. 11-1112-RGA, D.I. 40; No. 13-52-RGA, D.I. 177, 178; No. 13-527-RGA; No. 14-777-RGA). Novartis Pharmaceuticals Corporation is incorporated in Delaware and researches, markets, and sells prescription drugs. (D.I. 28 at p. 2; D.I. 29 at 1). Novartis AG and Novartis Pharma AG are Swiss companies with a principal place of business in Basel, Switzerland. (D.I. 28 at p. 2). LTS Lohmann Therapie-Systeme AG is a German company with its principal place of business in Germany. (D.I. 28 at p. 2).

Defendants have moved to dismiss the complaint for lack of personal jurisdiction. (D.I. 15). Defendants Zydus Pharmaceuticals and Cadila also moved to dismiss the complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(2), and Cadila moved to dismiss for insufficient service of process under Rule 12(b)(5). (D.I. 15 at 6). The Court granted a stipulation to dismiss the complaint against defendants Zydus Pharmaceuticals and Cadila. (D.I. 24, 22).¹ The remaining defendant is Zydus Noveltch. Therefore, the only remaining

¹ The stipulation included, inter alia, an agreement that Zydus Pharmaceuticals and Cadila would provide discovery as if they were parties and that these two defendants consent to jurisdiction only to enforce the stipulation, and nothing more. (D.I. 22 at 2-3).

issue for this Court is whether there is personal jurisdiction over Defendant Zydus Noveltech. (See D.I. 28 at p.1 n. 1).

Zydus Noveltech is a New Jersey corporation with a principal place of business in Vermont. (D.I. 18 at 1; *see also* D.I. 47 at 6). Zydus Pharmaceuticals and Zydus Noveltech are sister companies, and Cadila is their ultimate parent company.² (D.I. 33 at 6). The majority shareholder of Zydus Noveltech is Zydus International Private Ltd., a subsidiary of Cadila. (D.I. 18 at 2). Zydus Noveltech has no property, personnel, or offices in Delaware, does not sell any products in Delaware, and does not conduct any business in Delaware. (D.I. 18 at 1). Zydus Noveltech is not registered to do business in Delaware. (D.I. 47 at 13). Zydus Noveltech prepared and submitted the ANDA, but no work to prepare the product or ANDA was conducted in Delaware. (D.I. 18 at 2). Defendant sent its ANDA notice letter on July 16, 2014 to Plaintiffs in Switzerland, Germany, and New Jersey. (D.I. 34-1 at 2-3). This is the first ANDA case that Defendant has been involved in, although its sister company Zydus Pharmaceuticals has appeared before this Court. (D.I. 47 at 6).

There is a dispute among the parties about whether Defendant's generic drug at issue will make it to market in Delaware. Plaintiffs argue that Defendant will sell generic copies of the Exelon product in Delaware, through its sister company Zydus Pharmaceuticals (D.I. 28 at pp. 3-

² According to Defendant, Zydus Noveltech focuses primarily on transdermal drug products, such as the technology at issue in this case, while Zydus Pharmaceuticals sells oral products. (D.I. 33 at 6). Defendant explains: "While the two companies share the same ultimate parent corporation (Cadila), Zydus Pharmaceuticals has no connection to the generic rivastigmine patch at issue in this case and Novartis has no basis for asserting that Zydus Pharmaceuticals will eventually sell Zydus Noveltech's generic rivastigmine patch (assuming approval by the FDA)." (D.I. 33 at 6).

8), though Defendant calls these allegations “mere speculation.”³ (D.I. 33 at 6). Defendant questions the proposition that it will sell products in Delaware in the future: “Novartis has no evidence that Zydus Noveltch will sell products in Delaware in the future; there is no contractual obligation or other evidence to support Novartis’s argument.” (D.I. 33 at 12).

I. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(2), a party may move to dismiss a case because the court lacks personal jurisdiction over that party. “Once challenged, the plaintiff bears the burden of establishing personal jurisdiction.” *O’Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 316 (3d Cir. 2007). Absent an evidentiary hearing, a plaintiff needs only to establish a prima facie case of personal jurisdiction, and the plaintiff is entitled to have its allegations taken as true and factual disputes drawn in its favor. *Id.*

Personal jurisdiction derives from two sources, statutory and constitutional law. A district court must determine whether the state’s long-arm statute permits service of process, and whether asserting personal jurisdiction would violate due process. *See Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1359 (Fed. Cir. 2001). When determining whether a district court properly decided personal jurisdiction, the Federal Circuit applies its own law, not regional circuit law, because the jurisdictional issue is “intimately involved with the substance of the patent laws.” *Id.* (citations omitted) (internal quotation marks omitted). Delaware’s long-arm statute has been construed “broadly to confer jurisdiction to the maximum extent possible under the Due Process

³ Plaintiffs’ position on the role of the sister company Zydus Pharmaceuticals seems incorrect. It seems clear that Zydus Pharmaceuticals has no involvement with the rivastigmine product, and because it focuses only on oral drugs, likely would not be involved in the future. (D.I. 33 at 6 (citing D.I. 18 at ¶ 8)). By what means Zydus Noveltch would sell the product in Delaware in the future seems to be an open question.

Clause, so the focus of the inquiry traditionally rests on the constitutional component.”

AstraZeneca AB v. Mylan, 2014 WL 5778016, at *2 (D. Del. Nov. 5, 2014) (internal quotation marks omitted) (citations omitted).⁴

Due process requires “minimum contacts” between an out-of-state defendant and the forum “such that maintenance of the suit does not offend traditional notions of fair play and substantial justice.” *Int’l Shoe Co. v. State of Wash., Office of Unemployment Comp. & Placement*, 326 U.S. 310, 316 (1945) (internal quotation marks omitted) (internal citations omitted). General jurisdiction occurs where a defendant’s contacts with a state are “so continuous and systematic as to render it essentially at home in the forum State.” *Daimler AG v. Bauman*, 134 S. Ct. 746, 761 (2014) (internal quotation marks omitted). Specific jurisdiction occurs when a defendant has “purposefully directed his activities at residents of the forum, and the litigation results from alleged injuries that arise out of or relate to those activities.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (internal citations omitted) (internal quotation marks omitted).

The Supreme Court has recently explained that “specific jurisdiction has become the centerpiece of modern jurisdiction theory, while general jurisdiction has played a reduced role.” *Daimler AG v. Bauman*, 134 S. Ct. 746, 755 (2014) (internal quotation marks omitted). The Supreme Court has stressed the difference between the specific and general jurisdiction inquiries. *See Daimler AG*, 134 S. Ct. at 757 (“Although the placement of a product into the stream of

⁴ This Court tends to agree with Judge Sleet that it is not entirely clear whether Delaware’s long-arm statute extends as far as allowed by the constitutional component. *See AstraZeneca*, 2014 WL 5778016, at *2 n. 1; *see also Commissariat A L’Energie Atomique v. Chi Mei Optoelectronics Corp.*, 395 F.3d 1315, 1322 (Fed. Cir. 2005) (“Delaware law is also unclear as to whether or not the long arm statute is coextensive with the due process clause.”). As in *AstraZeneca*, because the parties have not challenged the limits of Delaware’s long-arm statute, this Court will focus the inquiry on the constitutional analysis.

commerce may bolster an affiliation germane to specific jurisdiction, we explained, such contacts do not warrant a determination that, based on those ties, the forum has general jurisdiction over a defendant. As *International Shoe* itself teaches, a corporation's continuous activity of some sorts within a state is not enough to support the demand that the corporation be amenable to suits unrelated to that activity." (internal quotation marks omitted) (citations omitted)).

II. DISCUSSION

In recent proceedings, the judges in this District have grappled with personal jurisdiction for ANDA suits with similar, albeit not identical, fact patterns.⁵ While I expect there will soon be guidance from the Federal Circuit on this issue,⁶ I believe careful recitation of the facts and analysis of the cases on appeal is instructive to the present matter.⁷

In *AstraZeneca AB v. Mylan Pharmaceuticals*, 2014 WL 5778016, at *7 (D. Del. Nov. 5, 2014), Judge Sleet found that the act of filing an ANDA and a paragraph IV notification provided sufficient minimum contacts with Delaware for specific jurisdiction, denying a motion

⁵ In *Novartis Pharmaceuticals Corp. v. Mylan Inc.*, 2015 WL 1246285, at *3-5 (D. Del. March 16, 2015), I explicitly adopted Judge Stark's reasoning in *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, 2015 WL 186833 (D. Del. Jan. 14, 2015), finding that Defendant Mylan Pharmaceuticals consented to general jurisdiction by complying with Delaware registration statutes. I also permitted jurisdictional discovery to determine if there was specific jurisdiction over Mylan Inc.

While *AstraZeneca* and *Acorda* may differ in their analysis with respect to consent and general jurisdiction, they are consistent in their analysis on specific jurisdiction. Only specific jurisdiction is at issue in the present matter.

⁶ Both *AstraZeneca* and *Acorda* are on interlocutory appeal. (Nos. 15-1460, 15-1456).

⁷ As I was preparing to file this Memorandum Opinion and Order, Judge Robinson issued *Purdue Pharma L.P. v. Collegium Pharma, Inc.*, Civ. No. 15-260-SLR, D.I. 29 (D. Del. August 6, 2015), which has analogous facts and reaches the same conclusion.

to dismiss for lack of personal jurisdiction. In that case, Plaintiff AstraZeneca AB was a Swedish company with its principal place of business in Sweden, and its U.S. subsidiary, AstraZeneca Pharmaceuticals LP was a limited partnership operating under the laws of Delaware with its principal place of business in Delaware. *Id.* at *1. Plaintiff filed a patent infringement suit in the District of Delaware triggered by two ANDAs filed by Defendant, Mylan, which was incorporated in West Virginia with its principal place of business also in West Virginia. *Id.* at *1. Mylan had no property or employees in Delaware; however, it was registered to do business in Delaware and had appointed a registered agent to accept process in Delaware. *Id.* at *1. The ANDAs at issue were prepared in West Virginia and filed in Maryland with the FDA. *Id.* at *1. Mylan sent its paragraph IV certification to AstraZeneca U.S. in the state of Delaware. *Id.* at *7. Mylan had previously litigated in the District of Delaware numerous times. *Id.* at *1. Judge Sleet found that there was no general jurisdiction over Mylan because Plaintiff failed to allege facts that Mylan was “essentially at home” in Delaware. *Id.* at *3-4. Judge Sleet also found that Mylan’s compliance with Delaware registration statutes to do business in the state did not constitute consent to general jurisdiction. Judge Sleet, however, found that the act of filing an ANDA and the paragraph IV letter mailed to Delaware provided minimum contacts with Delaware to support specific jurisdiction. *Id.* at *7. Judge Sleet’s specific jurisdiction analysis relied in part on the uniqueness of the Hatch-Waxman Act, which makes patent litigation expected as part of the FDA approval process for generic drugs. *Id.* at *6. Therefore, Plaintiff’s cause of action was triggered by Mylan’s artificial injury against Plaintiff in Delaware. *Id.* at *7.

In *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, 2015 WL 186833, at *7-19 (D. Del. Jan. 14, 2015), Judge Stark determined that there was personal jurisdiction in an ANDA case against one defendant because it had consented to personal jurisdiction and because there

was specific jurisdiction. Plaintiff Acorda was a Delaware corporation with a principal place of business in the state of New York. *Id.* at *1. Plaintiff Alkermes was an Ireland corporation with a principal place of business also in Ireland. *Id.* at *1. Defendant Mylan Pharma was a West Virginia corporation with a principal place of business also in West Virginia. *Id.* at *2. Mylan Pharma was registered to do business in Delaware, had a registered agent to accept process in Delaware, and had litigated extensively in the District. *Id.* at *2. Mylan Pharma was a subsidiary of Mylan Inc., a Pennsylvania corporation with a principal place of business in Pennsylvania. *Id.* at *3. Mylan Inc. was not registered to do business in Delaware, though it has litigated in the District. *Id.* at *3. Neither Mylan Pharma nor Mylan Inc. had offices or property in Delaware. *Id.* at *3. Mylan Pharma prepared its ANDA filing in West Virginia and sent its ANDA notice letter to plaintiffs in New York and Ireland. Judge Stark determined both defendants were not “at home” in Delaware, meaning there could be no general jurisdiction on that ground. *Id.* at *7. Judge Stark, however, did determine that the court could exercise general jurisdiction over Mylan Pharma because it consented to such jurisdiction when it complied with Delaware registration laws and appointed an agent to accept service of process. *Id.* at *11. Judge Stark found that this consent to general jurisdiction did not extend to Mylan Inc. even though Mylan Pharma was its wholly-owned subsidiary. *Id.* at *15.

Judge Stark determined that there was specific jurisdiction over Mylan Pharma because it directed activities to Delaware, including sending a notice letter to a Delaware corporation, which had already initiated litigation against others to enforce its patents, something Defendant knew or should have known. *Id.* at *16. Judge Stark found that Mylan Pharma had also directed activities toward Delaware such as registering to do business in the state, appointing a registered agent to accept process, and had been a frequent litigant, particularly in ANDA litigation. *Id.* at

*16. Comparing the facts with Judge Sleet's decision in *AstraZeneca*, Judge Stark determined that the absence of mailing a paragraph IV certification into Delaware did not eliminate the possibility of exercising specific jurisdiction. *Id.* at *18. Judge Stark recognized that Plaintiff, as a Delaware corporate citizen, felt an injury when its patents were artificially infringed by an ANDA filing in Delaware. *Id.* at *18. Because Mylan Inc. was not registered to do business in Delaware, and was not involved in the ANDA filing, Judge Stark determined that those facts were not sufficient to establish specific jurisdiction. *Id.* at *19-20. However, Judge Stark did permit jurisdictional discovery to determine whether the agency relationship between Mylan Inc. and Mylan Pharma allows the Court to exercise personal jurisdiction over Mylan Inc. *Id.*

A. General Jurisdiction

This Court cannot exercise general jurisdiction over Zydus Noveltch because it is not "essentially at home" in Delaware. *See Daimler AG*, 134 S. Ct. at 761. Zydus Noveltch is not a Delaware corporation and this state is not its principal place of business. It has no property, staff or offices in the state and does not conduct any business here. Defendant has not registered to do business in Delaware, and thus no consent to general jurisdiction similar to that in *Acorda* can be found. No work related to preparing the ANDA or product was conducted in the state. The only fact of relevance is that Defendant directed an ANDA notice letter at Plaintiffs, which is not relevant for the general jurisdiction inquiry. Plaintiffs do not dispute the lack of general jurisdiction. Their briefing only addresses specific jurisdiction. Therefore, there is no general jurisdiction over Zydus Noveltch because there are no facts that demonstrate that Defendant is essentially at home here.⁸

⁸ This result is consistent with the positions recently taken in similar cases by this District, where no general jurisdiction was found. *See Acorda*, 2015 WL 186833, at *7; *AstraZeneca AB*, 2014 WL 5778016, at *4; *Novartis v. Mylan*, 2015 WL 1246285, at *7. While consent to general

B. Specific Jurisdiction

In essence, Plaintiffs argue that there is specific jurisdiction over Zydus Noveltech for two reasons: first, Zydus Noveltech directed its notice of ANDA filing to Novartis Pharmaceuticals, a Delaware corporation; and second, Zydus Noveltech will eventually, if authorized by the FDA, sell its generic product in Delaware. (D.I. 28 at p. 8).

Comparing the present matter with *Acorda* and *AstraZeneca*, Plaintiffs argue that Defendants directed harm into Delaware and should have reasonably anticipated suit. (D.I. 28 at p. 9). Plaintiffs argue that Novartis Pharmaceuticals, as a Delaware corporation, suffers injury from the filing of the ANDA. (D.I. 28 at p. 10). Because Novartis had already filed nine lawsuits against five groups of generic drug companies to enforce these patents in the District of Delaware, Zydus Noveltech knew or should have known that it would have been sued in Delaware. (D.I. 28 at pp. 10-11). Defendant responds that Plaintiffs' position would result in personal jurisdiction for an ANDA defendant where the plaintiff is incorporated, no matter how limited contacts are to the forum state. (D.I. 33 at 7). Defendant also argues that Plaintiffs are not injured in Delaware, because, if Plaintiffs are injured, the location of such an injury would be where the ANDA was prepared and submitted, or Vermont. (D.I. 33 at 7-8). Defendant argues that sending a notice letter to Novartis Pharmaceuticals, a Delaware corporation, at its offices in New Jersey is not sufficient to establish jurisdiction in Delaware. (D.I. 33 at 9-10). Finally, Defendants argue that any arguments about judicial efficiency cannot be used to establish jurisdiction when there is a complete lack of minimum contacts by Defendant. (D.I. 33 at 10-11).

jurisdiction was found in *Acorda*, 2015 WL 186833, at *11 and *Forest Labs., Inc. v. Amneal Pharm. LLC*, 2015 WL 880599, at *15 (D. Del. Feb. 26, 2015), that line of analysis is not applicable here because Zydus Noveltech has not registered to do business in Delaware.

Next, Plaintiffs argue that once Defendant's ANDA is approved it will sell generic Exelon products in Delaware or direct them to Delaware. (D.I. 28 at p. 13-15). Plaintiffs note that in non-ANDA cases an accused infringer is subject to suit wherever its products are sold, and absent that same result, an ANDA filer would be "insulated" from suit while it filed an infringing ANDA. (D.I. 28 at p. 16). Finally, Plaintiffs argue that an agency theory of personal jurisdiction, which attributes the activities of Zydus Noveltch's affiliates to it, is appropriate. (D.I. 28 at pp. 19-20).

Defendant argues that Plaintiffs' theory that there is jurisdiction based on futures sales should fail. (D.I. 33 at 11). Defendant argues that the nature of ANDA litigation means there will never be an infringing sale in Delaware because if this Court finds infringement it will order the FDA not to approve the ANDA until the valid patents expire; likewise, if the Court finds no infringement, then any future sales in Delaware will be noninfringing. (D.I. 33 at 12). It is speculative that Defendant will sell infringing products because Plaintiffs have offered no evidence that Defendant will sell products in Delaware. (D.I. 33 at 12). Finally, Defendants argue that there is no basis for jurisdiction from affiliates such as Zydus Pharmaceuticals because the two companies do not operate in concert with one another or have any agreements with each other over this technology. (D.I. 33 at 9).

Defendant's activities have not been purposefully directed at Delaware such that this Court can exercise specific jurisdiction over it. *See Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985). Zydus Noveltch has not registered to do business in Delaware, and does not have an agent to accept process in the state. Zydus Noveltch has not previously litigated in Delaware at all—let alone in the ANDA context. Defendant probably anticipated being sued in Delaware, as Plaintiffs had already brought multiple cases involving the same patents in

Delaware, but Defendant's anticipation is not by itself significant for the specific jurisdiction analysis.⁹ See *Novartis*, 2015 WL 1246285, at *3 n. 6. Defendant has no property, staff or offices in the state and does not conduct any business here. No work related to preparing the ANDA or product was conducted in this District.

At this time, there is no support for the argument that Defendant will sell infringing products in Delaware—and that idea appears to be only attorney argument. There are no facts to even suggest that Defendant will sell or direct its products to Delaware, and at this time, such an argument is entirely speculative for a specific jurisdiction analysis.

Unlike *AstraZeneca* and *Acorda*, the only fact that provides a jurisdictional hook here is that Defendant directed an ANDA notice to Plaintiffs, albeit to Plaintiffs in Switzerland, Germany, and New Jersey—not Delaware. In *AstraZeneca*, Judge Sleet found that sending a letter to Delaware was directing activities to Delaware; Judge Stark in *Acorda* determined that not sending the ANDA notice letter to Delaware did not foreclose a specific jurisdiction analysis. This Court believes those positions are reconcilable; where the ANDA letter is sent by itself is not determinative, but it is an additional fact demonstrating activity relevant to establishing personal jurisdiction.

Specific jurisdiction cannot be exercised merely because an ANDA notice letter was sent to a Delaware corporation, in another state, because to do so would offend traditional notions of fair play and substantial justice. A Delaware plaintiff's contacts—its injury—with Delaware may be relevant to the specific jurisdiction inquiry. *Acorda*, 2015 WL 186833, at *18. Personal jurisdiction, however, cannot be governed solely by a plaintiff's conduct. See, e.g., *Walden v.*

⁹ While true that Defendant's sister company Zydus Pharmaceuticals has appeared before this Court in ANDA litigation, it is too tenuous for this Court to import that history onto Defendant absent additional facts. (D.I. 47 at 6).

Fiore, 134 S. Ct. 1115, 1122 (2014) (internal citations omitted) (internal quotation marks omitted). (“...the relationship must arise out of contacts that the ‘defendant himself ‘ creates with the forum State. Due process limits on the State’s adjudicative authority principally protect the liberty of the nonresident defendant—not the convenience of plaintiffs or third parties. We have consistently rejected attempts to satisfy the defendant-focused ‘minimum contacts’ inquiry by demonstrating contacts between the plaintiff (or third parties) and the forum State.”); *see also Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994) (“...analysis of long-arm jurisdiction has its focus on the conduct of the defendant. Plaintiff’s contacts with the forum—such as where the plaintiff resides—as a general proposition are not considered a determinative consideration.”). Instead, the inquiry must focus on Defendant’s conduct and contacts with the forum. To allow jurisdiction in the present matter would not be consistent with the doctrine of specific jurisdiction. It would subject a defendant in an ANDA suit to personal jurisdiction anywhere a plaintiff is incorporated, regardless of the Defendant’s activities and contacts with that forum. Such an outcome would offend traditional notions of fair play and substantial justice.

Even though Plaintiffs have been injured, it does not follow that the location of that injury is in Delaware merely because an ANDA notice letter was sent elsewhere, to a company incorporated here. Both Judge Sleet in *AstraZeneca* and Judge Stark in *Acorda* found in part that specific jurisdiction was proper because an ANDA letter triggered an artificial injury against a plaintiff in Delaware. *AstraZeneca*, 2014 WL 5778016, at *7; *Acorda*, 2015 WL 186833, at *18. In Judge Stark’s case he determined that specific jurisdiction was proper even though an ANDA letter was sent to a Delaware corporation in another jurisdiction, considering additional activities directed at the state, none of which exist in the present matter. There is no question that

infringement in ANDA cases under §271(e)(2) is a “highly artificial act of infringement,” which allows a patent owner to initiate a lawsuit within 45 days to prevent approval for 30 months (or until a court determines that the patent is not infringed, if that occurs before the 30 months has passed). *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677-78 (1990); *see also Zeneca v. Mylan Pharmaceuticals*, 173 F. 3d 828 at 832-33 (Fed. Cir. 1999); *see also AstraZeneca*, 2014 WL 5778016, at *6 (“ANDA litigation is unlike other patent infringement litigation: The injury is abstract, making it difficult to point to a location out of which the injury ‘arises’ for jurisdictional purposes. At the same time, defending against an infringement lawsuit is an inherent and expected part of the ANDA filer’s business. To put it simply: a lawsuit is often inevitable, but it is not clear where it should be held.”). It is beyond dispute that the ANDA process triggered an injury, and that the submission of the ANDA letter triggered an injury against Plaintiff.¹⁰ It does not follow that that injury should be where the Plaintiff is incorporated, Delaware, rather than where the letter was directed, New Jersey.¹¹ Defendant directed activity to New Jersey, not Delaware. A Plaintiff cannot then transport that activity to its place of incorporation. The ANDA process may be unique in how it triggers injury in the

¹⁰ There has been some dispute among district courts about where the situs of injury is with an ANDA filing, whether it is where it was prepared or the generic drugs tests occurred, or whether the relevant location is to where the ANDA and notice letter are sent. *See AstraZeneca*, 2014 WL 5778016, at *7 n. 3. In the present case, either inquiry demonstrates the injury did not occur in Delaware; the ANDA was not prepared in Delaware and the paragraph IV notification was not directed to Delaware.

¹¹ In *AstraZeneca*, Judge Sleet suggested that the defendant’s position that Delaware, where the ANDA notice letter was sent, did not have personal jurisdiction implied that under such a theory there could be no appropriate location for jurisdiction. 2014 WL 5778016, at *7. Judge Sleet, therefore, found that the only appropriate forum was the residence of the patent holder. In the present matter, however, because the letter was sent to New Jersey, and not Delaware, such an argument would not be relevant.

patent context, but it must be subject to the same rules that govern personal jurisdiction. Even though the act of filing the ANDA and the paragraph IV notification constitute an injury,¹² neither was directed at Delaware because Defendant sent its letter to Plaintiffs abroad and in New Jersey. Therefore, this Court cannot exercise specific personal jurisdiction over Defendant.¹³

III. CONCLUSION

For the above reasons, Defendants' Motion to Dismiss (D.I. 14) is granted.¹⁴ An appropriate order will follow.

¹² Both parties have cited to authority on issues that are similar, but not entirely on point. For example, the Federal Circuit in *Zeneca* determined that Maryland, the location of the government agency that received ANDAs, could not exercise personal jurisdiction over a party. 173 F.3d at 832. But that analysis was based at least in part on the government contacts exception, where petitioning the national government does not count as jurisdictional conduct. *Id.* at 831-32. Here, where the central jurisdictional fact is the filing of the ANDA notice letter to Plaintiffs, not filing the ANDA with the government, that case does not provide much guidance.

Similarly, Defendants cite to *Campbell Pet Co. v. Miale*, 542 F. 3d 879, 885-86 (Fed. Cir. 2008) where the Federal Circuit explained that in the declaratory judgment context, merely sending an infringement letter, without more, is an insufficient basis to exercise personal jurisdiction. It is hard to draw much from this in the context of the Hatch-Waxman Act, a very specific and unique statutory scheme.

¹³ Plaintiffs request jurisdictional discovery if "the Court is inclined to grant [Defendant's] motion." (D.I. 28 at p. 4 n. 4). Defendant objects, suggesting such discovery would be futile. (D.I. 33 at 14). There is nothing in the record that suggests jurisdictional discovery would establish a relationship between Zydus Noveltech and Zydus Pharmaceuticals such that there would be specific jurisdiction over Zydus Noveltech. Thus, the proposed discovery would be futile. *See Toys R Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003).

¹⁴ The result of cases like this one could be significant inefficiency and waste of judicial resources because ANDA litigation often involves many generic filers.